IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P.; NESTLÉ SKIN HEALTH S.A.; and TCD ROYALTY SUB, LLC, Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS CO. (I) PVT. LTD., Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiffs Galderma Laboratories, L.P. ("Galderma"), Nestlé Skin Health S.A. ("NSH") and TCD Royalty Sub, LLC ("TCD") (collectively, "Plaintiffs"), for their Complaint against Defendants Amneal Pharmaceuticals, LLC ("Amneal Pharma") and Amneal Pharmaceuticals Co. (I) Pvt. Ltd. ("Amneal India") (collectively, "Amneal" or "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Galderma is a privately held partnership registered in the State of Texas, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

2. Plaintiff NSH is a "société anonyme" organized and existing under the laws of Switzerland, having a principal place of business at Avenue Gratta Paille 2, 1018 Lausanne, Switzerland.

3. Plaintiff TCD is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 222 Delaware Avenue, Suite 1200, Wilmington, DE 19801.

4. Upon information and belief, Defendant Amneal Pharma is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 85 Adams Avenue, Hauppauge, NY 11788.

5. Upon information and belief, Defendant Amneal India is an Indian corporation and a wholly-owned subsidiary and agent of Defendant Amneal Pharma, having a principal place of business at 882/1-871, Village: Rajoda, Near Hotel Kankavati, Taluka: Bavla, District: Ahmedabad-382220, Gujarat, India.

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent Nos. 7,211,267 ("the '267 patent"); 7,232,572 ("the '572 patent"); 8,603,506 ("the '506 patent"); 9,241,946 ("the '946 patent"); 7,749,532 ("the '532 patent"); 8,206,740 ("the '740 patent"); 8,394,405 ("the '405 patent"); 8,394,406 ("the '406 patent"); 8,470,364 ("the '364 patent"); and 8,709,478 ("the '478 patent") (collectively, "the patents-in-suit"). (Exhibits A-J.) This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

9. This Court has personal jurisdiction over Amneal Pharma because, *inter alia*, it is a Delaware company.

10. This Court has personal jurisdiction over Defendants Amneal Pharma and Amneal India by virtue of the fact that, *inter alia*, Defendants have committed, aided, abetted, contributed

to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. Defendants state that they intend to engage in the commercial manufacture, use, and/or sale under Amneal's Abbreviated New Drug Application ("ANDA") No. 203278 of a 40 mg doxycycline oral capsule product proposed for the indication of "treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients" ("Amneal's ANDA Product"), before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

11. Upon information and belief, Amneal Pharma is the agent for Amneal India for purposes of making regulatory submissions to the United States Food and Drug Administration ("FDA"), including Amneal's ANDA No. 203278 at issue in this litigation.

12. Upon information and belief, Amneal Pharma and Amneal India have acted in concert with respect to the preparation and filing of ANDA No. 203278 for Amneal's ANDA Product and in preparation to sell the ANDA Product in the United States, including in the State of Delaware.

13. Upon information and belief, following approval of ANDA No. 203278 by the FDA, Amneal Pharma and Amneal India will act in concert to commercialize Amneal's ANDA Product throughout the United States, including in the State of Delaware.

14. Amneal's infringing activities with respect to its filing of ANDA No. 203278 and intent to commercialize Amneal's ANDA Product have led and/or will lead to foreseeable harm and injury to Plaintiffs, including to TCD, a Delaware company located in Wilmington, Delaware. Amneal's infringing activities are further connected to Delaware in that Amneal sent

its February 17, 2016 Notice Letter (as defined below) into Delaware, addressing it to TCD at its Wilmington, Delaware location.

15. This Court also has personal jurisdiction over Amneal Pharma and Amneal India by virtue of the fact that, upon information and belief, *inter alia*, Amneal Pharma and Amneal India have availed themselves of the rights and benefits of Delaware law, and have engaged in systematic and continuous contacts with the State of Delaware.

16. Upon information and belief, Amneal Pharma and Amneal India, directly or through their subsidiaries, affiliates or agents, develop, formulate, manufacture, market, import and sell pharmaceutical products, including branded drug products and generic drug products, throughout the United States, including in the State of Delaware.

17. This Court also has personal jurisdiction over Defendants Amneal Pharma and Amneal India because they have previously submitted to the jurisdiction of this Court and have affirmatively availed themselves of the legal protections of the State of Delaware, having asserted counterclaims against Galderma in this jurisdiction in a related patent infringement litigation previously before this Court regarding the same ANDA No. 203278 and a number of the same patents at issue in this Complaint. *See Galderma Labs. Inc. v. Amneal Pharm., LLC*, No. 11-cv-1106-LPS (D. Del.). Further, Amneal Pharma and Amneal India have asserted counterclaims in this jurisdiction in other matters. *See, e.g., Sanofi v. Amneal Pharm. LLC*, No. 14-cv-875-RGA (D. Del.); *Meda Pharm. Inc. v. Amneal Pharm. LLC*, No. 15-cv-617-GMS (D. Del.); *UCB Inc. v. Amneal Pharm. LLC*, No. 13-cv-1208-LPS (D. Del.); *Novartis Pharm. Corp. v. Amneal Pharm. LLC*, No. 15-cv-1025-RGA (D. Del.); *AstraZeneca LP v. Amneal Pharm. LLC*, No. 15-cv-1056-RGA (D. Del.); *AstraZeneca Pharm. LP v. Amneal Pharm. LLC*, No. 15-cv-1139-GMS (D. Del.); *AbbVie Inc. v. Amneal Pharm. LLC*, No. 12-cv-235-SLR

(D. Del.); *Forest Labs. Inc. v. Amneal Pharm. LLC*, No. 13-cv-1737-SLR (D. Del.); *Forest Labs. LLC v. Amneal Pharm. LLC*, No. 15-cv-430-SLR (D. Del.); *Prometheus Labs. Inc. v. Amneal Pharm. LLC*, No. 14-cv-968-LPS (D. Del.); *Teva Pharm. USA Inc. v. Amneal Pharm. LLC*, No. 15-cv-124-GMS (D. Del.); *Hospira Inc. v. Amneal Pharm. LLC*, No. 15-cv-697-RGA (D. Del.); *Forest Labs. LLC v. Amneal Pharm. LLC*, No. 15-cv-756-LPS (D. Del.); *AstraZeneca LP v. Sigmapharm Labs., LLC*, No. 15-cv-1000-RGA (D. Del.).

THE PATENTS-IN-SUIT

18. Plaintiff Galderma holds New Drug Application No. 50-805 on ORACEA® (doxycycline, USP) 40 mg Capsules, and is the exclusive distributor of ORACEA® Capsules in the United States.

19. On May 1, 2007, the ’267 patent, entitled “Methods of Treating Acne” was duly and legally issued to CollaGenex Pharmaceuticals, Inc. A copy of the ’267 patent is attached as Exhibit A.

20. NSH is the current owner of the ’267 patent.

21. On June 19, 2007, the ’572 patent, entitled “Methods of Treating Rosacea” was duly and legally issued to CollaGenex Pharmaceuticals, Inc. A copy of the ’572 patent is attached as Exhibit B.

22. NSH is the current owner of the ’572 patent.

23. On December 10, 2013, the ’506 patent, entitled “Methods of Treating Acne” was duly and legally issued to Galderma Laboratories, Inc. A copy of the ’506 patent is attached as Exhibit C.

24. NSH is the current owner of the ’506 patent.

25. On January 26, 2016, the ’946 patent, entitled “Methods of Treating Acne” was duly and legally issued to Galderma Laboratories, Inc. A copy of the ’946 patent is attached as Exhibit D.

26. NSH is the current owner of the ’946 patent.

27. On July 6, 2010, the ’532 patent, entitled “Once Daily Formulations of Tetracyclines” was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the ’532 patent is attached as Exhibit E.

28. TCD is the current owner of the ’532 patent.

29. On June 26, 2012, the ’740 patent, entitled “Once Daily Formulations of Tetracyclines” was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the ’740 patent is attached as Exhibit F.

30. TCD is the current owner of the ’740 patent.

31. On March 12, 2013, the ’405 patent, entitled “Once Daily Formulations of Tetracyclines” was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the ’405 patent is attached as Exhibit G.

32. TCD is the current owner of the ’405 patent.

33. On March 12, 2013, the ’406 patent, entitled “Once Daily Formulations of Tetracyclines” was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the ’406 patent is attached as Exhibit H.

34. TCD is the current owner of the ’406 patent.

35. On June 25, 2013, the ’364 patent, entitled “Once Daily Formulations of Tetracyclines” was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the ’364 patent is attached as Exhibit I.

36. TCD is the current owner of the '364 patent.

37. On April 29, 2014, the '478 patent, entitled "Once Daily Formulations of Tetracyclines" was duly and legally issued to Supernus Pharmaceuticals, Inc. A copy of the '478 patent is attached as Exhibit J.

38. TCD is the current owner of the '478 patent.

39. The patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for ORACEA® Capsules.

AMNEAL'S ANDA, NOTICE LETTERS, AND THE FIRST AMNEAL ACTION

40. Upon information and belief, Amneal Pharma, with the collaboration or assistance of Amneal India, submitted ANDA No. 203278 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), including a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Amneal's ANDA Product prior to the expiration of the patents-in-suit.

41. Upon information and belief, Amneal has stated that the proposed ANDA Product will be marketed for the currently approved indication for ORACEA® Capsules.

42. Amneal had previously sent a notice of Paragraph IV Certification under ANDA No. 203278 to Galderma and others, dated September 27, 2011, representing that Amneal was seeking approval of its ANDA Product under ANDA No. 203278 prior to the expiration of certain of the patents-in-suit, including the '267, '572, and '532 patents ("September 27, 2011 Notice Letter"). Amneal had also previously sent a notice of Paragraph IV Certification under ANDA No. 203278 to Galderma and others, dated September 14, 2012, representing that

Amneal was seeking approval of its ANDA Product under ANDA No. 203278 prior to the expiration of the '740 patent ("September 14, 2012 Notice Letter").

43. On November 8, 2011, Galderma, along with other parties, filed a Complaint in this Court against Amneal for infringement of the '267, '572 and '532 patents. *See* D.I. 1, *Galderma Labs. Inc. v. Amneal Pharm., LLC*, No. 11-cv-1106-LPS (D. Del.) ("First Amneal Action"). On July 24, 2012, Galderma and its co-plaintiffs filed a First Supplemental Complaint against Amneal in the First Amneal Action for infringement of the '740 patent. *See* D.I. 74, *Galderma Labs. Inc. v. Amneal Pharm., LLC*, No. 11-cv-1106-LPS (D. Del.). The parties submitted a Proposed Joint Pretrial Order on April 29, 2014, with trial scheduled to begin on June 2, 2014. *See* D.I. 214, *Galderma Labs. Inc. v. Amneal Pharm., LLC*, No. 11-cv-1106-LPS (D. Del.).

44. On May 13, 2014, Amneal amended its ANDA No. 203278 to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") such that Amneal no longer sought approval from FDA to market a product pursuant to ANDA No. 203278 prior to the expiration of the '532 patent and the '740 patent. On May 16, 2014, based on Amneal's Paragraph III Certification, the parties to the First Amneal Action, including Galderma Laboratories, L.P. and Amneal, entered into a Joint Stipulation of Dismissal Without Prejudice of Plaintiffs' Claims and Defendants' Counterclaims. *See* D.I. 222, *Galderma Labs. Inc. v. Amneal Pharm., LLC*, No. 11-cv-1106-LPS (D. Del.). The Court closed the First Amneal Action that same day.

45. Upon information and belief, on January 29, 2016, Amneal received tentative approval from the FDA for its ANDA Product under ANDA No. 203278.

46. Amneal has now sent a letter to Galderma, NSH, and TCD dated February 17, 2016, signed by Candis Edwards, Senior Vice President – Regulatory Affairs, representing that Amneal has now filed a Paragraph IV Certification in ANDA No. 203278 with respect to the '267, '572, '506, '946, '532, '740, '405, '406, '364, and '478 patents, and that Amneal is again seeking approval of its ANDA Product under ANDA No. 203278 prior to the expiration of those patents ("the February17, 2016 Notice Letter").

47. The February 17, 2016 Notice Letter included an accompanying Offer of Confidential Access ("OCA") to certain Amneal confidential information regarding the Amneal ANDA Product. Galderma subsequently, over the course of several weeks, negotiated with Amneal in an effort to agree on reasonable terms for Amneal's OCA. The parties were not able to reach an agreement with respect to the reasonable revisions to the terms of Amneal's OCA that Galderma proposed.

48. To date, Amneal has not provided Plaintiffs with a copy of any portions of Amneal's ANDA (including amendments, supplements or correspondence created after the First Amneal Action and not previously available to Plaintiffs), or any information regarding the Amneal ANDA Product beyond the information that was set forth in Amneal's Notice Letter.

AMNEAL'S INFRINGEMENT OF THE PATENTS-IN-SUIT

49. Plaintiffs re-allege paragraphs 1-48 as if fully set forth herein.

50. By seeking approval of ANDA No. 203278 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Amneal's ANDA Product prior to the expiration of the '267, '572, '506, '946, '532, '740, '405, '406, '364, and '478 patents, Amneal has infringed those patents-in-suit under 35 U.S.C. § 271(e)(2)(A).

51. Defendants Amneal Pharma and Amneal India are jointly and severally liable for infringement of the ’267, ’572, ’506, ’946, ’532, ’740, ’405, ’406, ’364, and ’478 patents under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Amneal Pharma and Amneal India actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of ANDA No. 203278 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Amneal’s ANDA Product prior to the expiration of the patents-in-suit.

52. Moreover, if Amneal manufactures, uses, offers for sale, or imports into the United States any of the Amneal ANDA Product, or induces or contributes to any such conduct, prior to the expiration of the ’267, ’572, ’506, ’946, ’532, ’740, ’405, ’406, ’364, and ’478 patents, including any applicable exclusivities or extensions, Amneal would infringe the one or more claims of those patents-in-suit under 35 U.S.C. § 271(a), (b) and/or (c).

53. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 203278 be a date that is not earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiffs become entitled.

54. Plaintiffs will be irreparably harmed by Amneal’s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

A. An Order adjudging and decreeing that Defendants Amneal Pharma and Amneal India have infringed the ’267, ’572, ’506, ’946, ’532, ’740, ’405, ’406, ’364, and ’478

patents by submitting ANDA No. 203278 to FDA and seeking FDA approval of ANDA No. 203278 prior to the expiration of those patents;

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Amneal's ANDA No. 203278 will not be earlier than the expiration date of the '267, '572, '506, '946, '532, '740, '405, '406, '364, and '478 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents-in-suit to which Plaintiffs are or become entitled;

C. An Order permanently enjoining Defendants Amneal Pharma and Amneal India, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from manufacturing, using, offering to sell, selling, marketing, distributing, or importing Amneal's ANDA Product identified in this Complaint, or any product that infringes the '267, '572, '506, '946, '532, '740, '405, '406, '364, or '478 patents, prior to the expiration of the patents-in-suit, including any extensions to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief to the extent Amneal commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States any product that infringes or induces or contributes to the infringement of the '267, '572, '506, '946, '532, '740, '405, '406, '364, or '478 patents, within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

E. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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